

DATA EVALUATION RECORD
AVIAN SINGLE-DOSE LD₅₀ TEST
GUIDELINE 71-1

1. CHEMICAL: MTI

Shaughnessey #: 107107

2. TEST MATERIAL: 2-Methyl-4,5-trimethylene-4-isothiazolin-3-one; Y06823/007/001; Bottle No. 092077; Batch NBY 2257/69 - MTI/SOL; purity 94.6%; tan powder

3. CITATION S. M. Campbell and J. B. Beavers. 1992. An Acute Oral Toxicity With the Northern Bobwhite. Wildlife International LTD. Project No. 123-167; Wildlife International LTD, 8598 Commerce Dr., Easton, MD 21691; Sponsored by ICI Specialty Chemicals, Wilmington, DE 19897; MRID 43138708

4. REVIEWED BY:

Joanne S. Edwards
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Signature: *Joanne S. Edwards*

Date: 11/31/95

5. APPROVED BY:

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Signature: *L. W. T.*

Date: 2/21/95

6. CONCLUSIONS: This study is scientifically sound and satisfies the guideline requirement (Gdln 71-1) for an avian acute LD₅₀ study. The single oral LD₅₀ for bobwhite quail exposed to MTI is 152 mg/kg (C.I 100 - 200 mg/kg). This classifies MTI as moderately toxic to birds.

7. ADEQUACY OF THE STUDY: Core

8. RATIONAL FOR CLASSIFICATION: N/A

9. BACKGROUND: New chemical registration.

10. MATERIALS AND METHODS:

A. Test Organisms:

Guideline Criteria	Reported Information
Species: A wild waterfowl species, preferably the mallard (<i>Anas platyrhynchos</i>), or an upland game bird species, preferably the bobwhite (<i>Colinus virginianus</i>).	Northern Bobwhite (<u>Colinus virginianus</u>)
Age at beginning of test: At least 16 weeks old.	22 wks; birds ranged in weight from 183 to 230 grams at test initiation
Supplier	Top Flight Quail Farm, Belvidere, NJ
Acclimation period: At least 15 days.	9 weeks

B. Test System:

Guideline Criteria	Reported Information
Pen facilities adequate?	yes; average temperature maintained at $22.1^{\circ}\text{C} \pm 1.5^{\circ}\text{C}$; relative humidity maintained at $80\% \pm 16\%$.
Photoperiod: 10-hr light : 14-hr dark is recommended.	8-hr light regime; fluorescent lighting; birds were exposed to approx. 257 lux of illumination
Diet was nutritious and appropriate for species?	yes; analysis of diet formulation included in report
Feed withheld at least 15 hours prior to dosing?	yes

C. Test Design:

Guideline Criteria	Reported Information
Range finding test?	no
Definitive Test Nominal concentrations: At least five, in a geometric scale, unless LD ₅₀ > 2000 mg AI / kg.	12.5, 25, 50, 100, 200 and 400 mg/kg a.i. (dosages were not corrected for purity of test substance)
Controls: water control or vehicle control (if vehicle is used)	control group dosed with diluent only (deionized water)
Number of birds per group: 10 (strongly recommended)	10 per group; (5 males and five females each) -indiscriminate draw; each group assigned to 2 pens (females in one; males in other)
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	deionized water used as vehicle
Amount of vehicle per body weight: Constant volume/weight % of body weight, not to exceed 1% (1ml/100g).	dosages were not adjusted to purity of test substance; concentration of the test substance in the diluent was adjusted to provide a constant volume to body wt dosage for all treatment birds
Observations period: At least 14 days.	14 days

Comments: A GLP Compliance Statement was included in the report indicating the study was conducted under GLP with the following exceptions: samples of dosing solutions were not collected for confirmation of the test concentrations, homogeneity or stability. Also, test substance characterization was performed by ICI Specialties and was not audited for compliance with Good Laboratory Practice Standards by Wildlife International Ltd. A Quality Assurance Statement was also included in the report.

11. REPORTED RESULTS:

Guideline Criteria	Reported Information
Individual body weights measured at beginning of test, on day 14 and at end of test if extended beyond 14 days?	body weights were measured at initiation and by group on days 3, 7, and 14
Mean feed consumption measured at beginning of test, on day 14, and at end of test if extended beyond 14 days?	determined for each group for days 0-3, 4-7, and 8-14; determined by measuring change in weight of the feed presented to the birds over given period of time
Control Mortality: Not more than 10%	none
Raw data included?	no
Signs of toxicity (if any) were described?	yes

Mortality:

Nominal (mg/kg)	Control	12.5	25	50	100	200	400
Measured (mg/kg)	-	-	-	-	-	-	-
No. dead / no. exposed	0/10	0/10	0/10	0/10	0/10	9/10	10/10

Reported Statistical Results: The LD₅₀ was determined to be approx. 152 mg/kg with 95% confidence limits of 100 mg/kg to 200 mg/kg. The no observed effect dosage was determined to be 25 mg/kg, based upon signs of toxicity noted at the 50 mg/kg dose level.

12. REVIEWER'S DISCUSSION AND INTERPRETATION

Verification of Statistical Results: The single oral LD₅₀ for

bobwhite quail exposed to MTI was verified to be using EEB's Toxanol program. An LD₅₀ of 152 mg/kg classifies MTI as moderately toxic to birds. The NOEC is 50 mg/kg.

Guideline Deviations:

The following deviation was noted. This did not affect the overall quality of the study:

o Group body weights, rather than individual body weights, were taken.

Classification: Core

Rationale: N/A

Reparability: N/A

13. COMPLETION OF ONE-LINER FOR STUDY: Yes

jedwards mti acute oral

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CONC.      NUMBER      NUMBER      PERCENT      BINOMIAL
           EXPOSED      DEAD        DEAD        PROB. (PERCENT)
400        10          10         100         9.765625E-02
200        10          9          90          1.074219
100        10          0          0           9.765625E-02
50         10          0          0           9.765625E-02
25         10          0          0           9.765625E-02
12.5       10          0          0           9.765625E-02
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THE BINOMIAL TEST SHOWS THAT 100 AND 200 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 152.1463

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

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